**The Southampton Clinical Trials Unit will be closed for trials enquiries over the Christmas period as follows:**

**From 5pm, Tuesday 22 December 2020
until 9am, Monday 4 January 2021**

**Individual trial arrangements including Patient Registration and Randomisation listed below.**

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| **Study** | **Closure Information** |
| **ACCEPT**  | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021.** **Clinical Queries*** **For clinical queries:** please contact Prof. Andy Davies (direct line 023 8120 8639, email: a.davies@soton.ac.uk or call Southampton General Hospital switchboard on 023 8077 7222 and ask for extension 8639.
* **For urgent eligibility queries and medical emergencies:** please ring Prof. Andy Davies (07976815095).

**SAE Reporting** * **Please continue to report SAEs and SUSARs by FAX during this period to 0844 774 0621.**

**Sample Shipment****HMDS** is also closed for the ACCEPT trial from 24Dec2020 – 02Jan2021 inclusive. Do not send samples during this time. Samples being sent on 22nd or 23rd December must be sent by courier to ensure they arrive before closure. |
| **AGILE CST-2** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021** * **For clinical queries:** please contact Prof Saye Khoo s.h.khoo@liverpool.ac.uk

**SAE Reporting** * Please continue to report SAEs and SUSARs on the RAVE system, or if unable to access, by FAX during this period to 0844 774 0621.
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| **ARGO**  | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021** **Clinical Queries*** **For clinical queries:** please contact Prof. Andy Davies (direct line 023 8120 8639, email: a.davies@soton.ac.uk or call Southampton General Hospital switchboard on 023 8077 7222 and ask for extension 8639.
* **For urgent medical emergencies:** please ring Prof. Andy Davies (07976815095).

**SAE Reporting** * **Please continue to report SAEs and SUSARs by FAX during this period to 0844 774 0621**
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| **BL13** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020 until 9am, Monday 4 January 2021****For URGENT clinical queries ONLY** please send an email to the following email address:- S.J.Crabb@southampton.ac.uk (Chief Investigator)**Please continue to report SAE’s or SUSARs in the RAVE database** by completing the eCRFwhich will be reviewed throughout the Festive period**.** If for any reason you are unable to access the database during this period, please report using the SCTU EMAIL or FAX to ctu@soton.ac.uk or 0844 774 0621**Southampton** **Tissue Bank**- **All sites sample shipments (not including Southampton)** – do not ship between 18 December and 3 January inclusive.**- Southampton sample shipments ONLY** – do not ship between the 22 December and 3 January inclusive. If a translational blood sample (STRECK tube) is collected, that cannot be shipped that day but can be shipped the next day, please place the sample in an appropriate, safe and secure fridge at site prior to shipping the next day. Samples must be shipped **within 24 hours** of blood draw. |

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| **CONFIRM** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021****Clinical Queries*** For **urgent clinical** queries, please contact Dean Fennell on 07870370708.

**Drug Ordering*** Monday 21st December - Last drug order requests processed.
* Monday 4th January – Normal shipping resumed

**SAE Reporting*** Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements, during the Christmas break.
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| **FACS** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021.** |
| **HARE-40** | The SCTU will be **closed** from **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021*** For urgent eligibility or clinical queries please contact the Chief Investigator, Prof Christian Ottensmeier on **07879 485 676**

**WISH lab** is also closed for the HARE-40 trial from **5pm, Tuesday 22 December 2020 until 9am, Monday 4 January 2021** inclusive. Advance notice of any samples over this period should be sent to Katy McCann K.J.McCann@soton.ac.uk and Celine Galloway C.Galloway@soton.ac.uk.  |
| **IELSG 37** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021**IELSG Switzerland will be **closed** for the Christmas holidays from 5 PM on Wednesday 23rd December 2020 until 9 AM on Monday 4th January 2021.* **For URGENT queries for IELSG 37 only**,  please contact:

Dr Andrew DaviesEmail:**a.davies@soton.ac.uk** Mobile : **07976815095**  |

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| **IELSG 32/42** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021**IELSG Switzerland will be **closed** for the Christmas holidays from 5 PM on Wednesday 23rd December 2020 until 9 AM on Monday 4th January 2021.* **For URGENT queries for IELSG 32/42 only** please contact:

Dr Kate CwynarskiEmail:**kate.cwynarski@nhs.net**Mobile : **07870638852** Please contact IELSG Switzerland for queries regarding IELSG 19, 26 or 32 |
| **MAPLE** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021.** **Patient registration:** Online patient registration can continue as normal. There will be no paper registration service (if required) during this time.**Blood samples:** The lab at HMDS is **closed** over Christmas and won’t receive blood samples from 5pm Wednesday 23rd December to 9am Monday 4th January 2021 inclusive. Therefore, no blood samples can be sent to HMDS by post after Monday 21st December, unless sent by courier to reach them on Tuesday 22nd or Wednesday 23rd December. You can resume sending samples as usual from Monday 4 January. **Tumour samples** can be sent at any time. |
| **MENAC** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021**For urgent **clinical** queries, please contact your PI in the first instance and then Barry Laird on barry.laird@ed.ac.uk or 07766 503 469For urgent trial queries, please contact the Norway trial team on menac@stolav.no. Please continue to report SAEs as normal. |

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| **Neo-AEGIS** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021**Patient registration for the Neo-AEGIS trial will close on Wednesday 23rd December at 5pm and reopen Monday 4th January 2021 at 9am. Any registrations received during this period will be processed on Monday 4th January.The emergency contact for the Neo-AEGIS trial during the CTU closure period will be Anna Shevlin - Anna.Shevlin@cancertrials.ie |
| **Orange II Plus** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021****For URGENT queries  contact** Robert Fichtinger, **robert.fichtinger@mumc.nl** or contact Prof John Primrose J.N.Primrose@soton.ac.uk or phone 07774840909* Please continue to report SAEs by scanning reports to **ctu@soton.ac.uk** as well as Robert Fichtinger, **robert.fichtinger@mumc.nl** during this period.
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| **ProCAID** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021****For URGENT queries ONLY** please send an email to all of the following email addresses:- S.J.Crabb@southampton.ac.uk (Chief Investigator)- procaid@soton.ac.uk **Please continue to report SAE’s or SUSARs by EMAIL or FAX during this period to ctu@soton.ac.uk or 0844 774 0621****Southampton** **Tissue Bank**- **All sites sample shipments (not including Southampton)** – do not ship between 18 December and 3 January inclusive.If a translational blood sample is collected, that cannot be shipped that day but can be shipped the next day, please place the sample in an appropriate, safe and secure fridge for the day the sample is held at site prior to shipping.If a translational blood sample is collected, that cannot be shipped for 2 or more days, please place the sample in an appropriate, safe and secure -80 freezer and let the ProCAID Team know that this has been undertaken. DO NOT ship these frozen samples until you have received confirmation from SCTU. |

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| **ProCAID Cont’d** | **Fisher (IMP shipments)** Fisher will not be closed over the Christmas period.**Cenduit (IWRS)**For any Cenduit queries, please contact the Helpdesk on 01403 342316 (open 24/7, 365).  |
| **RiVa** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021****For urgent queries only**, please contact Chief Investigator Sean Lim, S.H.Lim@soton.ac.uk * **Please continue to report SAEs and SUSARs by FAX during this period to 0844 774 0621.**

**WISH lab** is available to receive samples by prior agreement. Please contact wishsamples@soton.ac.uk **and** A.R.Coleman@soton.ac.uk to arrange receipt and please **DO NOT** send samples unless confirmation has been received. **TENALEA** can be accessed as normal during the Christmas break.**Celldex** will be taking orders of Varlilumab **until 18th Dec 2020**. For any participants registered between 19th Dec and 31st Dec Varlilumab should be ordered on the 4th Jan 2021.  |
| **SAFA** | The SCTU will be closed between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021.****Patients can continue to be registered during this time.****For trial clinical and eligibility queries,** please contact Professor Alison Layton * Phone: 07590 456 738
* Email: alison.layton1@nhs.net

**Please continue to report SAE’s or SUSARs by EMAIL or FAX during this period to ctu@soton.ac.uk or 0844 774 0621** |

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| **SupportBack2** | The SCTU will be **closed** between **5pm, Tuesday 22 December 2020until 9am, Monday 4 January 2021.*** **Please continue to report SAEs by FAX during this period to 0844 774 0621.**
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All staff of the SCTU would like to thank everyone
for their kind assistance and hard work.